

Appl. No. 10/658,736
Amdr dated April 3, 2009
Reply to Office Action of January 5, 2009

REMARKS

Applicants have carefully reviewed the Office Action mailed on January 5, 2009. Applicants respectfully traverse all objections, rejections and assertions made by the Examiner. Claims 20-29 are pending.

Claim Rejections under 35 U.S.C. § 103

Claims 20-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Mathews (U.S. Patent No. 6,033,406) in view of Haider (U.S. Patent No. 6,485,494 and Foley (U.S. Patent No. 5,792,044) and Davison (U.S. Patent Pub. No. 2001/0011170). This rejection is respectfully traversed. The Examiner acknowledges that Mathews fails to teach performing a multi-level fixation procedure, advancing a decompression tool to perform a decompression procedure, and inserting an access device and actuating the access device to a second configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of multiple vertebrae. The Examiner then asserts that it would have been obvious to one of ordinary skill in the art to perform the method of Mathews further including performing a multi-level fixation procedure in view of Haider, performing a decompression procedure in view of Foley, and inserting an access device in view of Davison in order to fix multiple joints of the spine. Applicants respectfully disagree and submit there is no motivation for one of ordinary skill in the art to combine the references because Mathews teaches away from the asserted combination.

Mathews teaches:

The fixation process is suprafascial that is above the muscle fascia, but subcutaneous, that is beneath the surface of the skin. Thus, none of the muscle tissue is destroyed and the subcutaneous nature of the procedure greatly decreases the risk of pin tract secretions or infections, or the potential of osteomyelitis.

See column 2, lines 4-9. Mathews also teaches:

Most significantly, the hardware resides within the suprafascial subcutaneous space 25 so that destruction of muscle tissue is not required. With this method, patient morbidity rates are reduced, while healing rates are improved. Since the fixation hardware resides above the muscle layer, removal can be conducted in an out-patient procedure under a local anesthetic.

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See column 7, lines 41-47. Mathews thus specifically teaches a subcutaneous method of installing fixation hardware above the muscle layer. As seen in the above quotes, Mathews provides advantages for performing the method in this manner. Applicants submit that Mathews teaches away from any modification of his method to include the multi-level polyaxial screw system of Haider or the access device of Davison et al. Haider appears to teach a fixation system in which screws and rods are inserted to the level of the pedicle, as shown in FIG. 1. Haider specifically teaches, "[t]he screw assembly of the present invention when secured in place does not protrude into the surrounding soft tissue"; see column 3, lines 50-52 and FIG. 1. Haider appears to teach inserting a screw and rod fixation system at the level of the pedicles, under the muscle. This appears to be in direct contradiction to the specific method steps taught by Mathews. Davison et al. appears to teach inserting an expandable device into an incision and expanding a distal portion of the device to provide "a significantly larger working area for the surgeon inside the body 130 within the confines of the cannula." See paragraphs 0031-0035 and FIGS. 1 and 5. Davison et al. appear to teach a device for expanding a surgical incision. Mathews specifically teaches a surgical procedure in which screws and plates or rods are inserted beneath the skin but above the muscle. Mathews teaches:

After the guide pin insertion process is complete, an incision is made at the guide pin insertion site, which, in one specific embodiment, is about 2.0 cm. in length. Then, using pick-ups and Metzenbaum scissors, subcutaneous tissue is dissected suprafascially. Metzenbaum scissors are also used to dissect the suprafascial subcutaneous tissues from the ipsilateral pin across the midline to the contralateral guide pin. Dissection of this tissue provides space for connection of pedicle screws in subsequent steps of the method.

See column 5, lines 34-42. Mathews thus teaches a specific method of dissecting the suprafascial space for connecting pedicle screws and a plate. Mathews also teaches inserting a three component tissue dilator system to create a path for inserting the self-tapping bone screw. See column 5, lines 43-59. Mathews thus already teaches specific method steps for achieving the desired suprafascial dissection and screw insertion. The access device of Davison et al. would not appear to be suitable for performing these specific method steps of Mathews. Further, because Mathews already teaches devices and methods for achieving the desired suprafascial dissection necessary for their specific method, there is no motivation for one of ordinary skill in

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the art to go against the teachings of Mathews to insert the screw and rod assembly of Haider or use the access device of Davison et al.

Applicants submit that there is no reasonable expectation of success for one of ordinary skill in the art to modify the method of Mathews to include the screw system of Haider and use the access device of Davison et al. because doing so would appear to destroy the functionality and advantages of the Mathews system and method. The Examiner asserts that because both Mathews and Haider teach methods of treating the spine including the use of a spinal fixation system it would have been obvious to one having ordinary skill in the art to substitute one spinal fixation system with the other in order to achieve the predictable results of immobilizing the spine during fusion of the spinal segments. Applicants respectfully disagree. As discussed above, Mathews teaches a specific screw and plate system designed for insertion suprafascially, under the skin but over the muscle. The screw and rod system of Haider appears to be designed to be inserted at the level of the pedicle, under the muscle. The fixation systems of Mathews and Haider thus do not appear to be interchangeable, and one of ordinary skill in the art would have no reasonable expectation of success in attempting to use the screws and rods of Haider in the suprafascial fixation method of Mathews. Foley does not appear to provide any motivation or expectation of success in modifying Mathews as suggested by the Examiner.

Mathews appears to teach away from any combination with Haider, Foley, and Davison et al., and further, there is no reasonable expectation of success. The only suggestion to combine the references appears to be in the instant specification, which is an improper basis for obviousness. Reconsideration and withdrawal of the rejection are respectfully requested.

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Conclusion

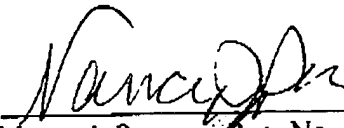
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Alan Shluzas et al.

By their Attorney,

Date: 4/3/09


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